



MAR 20 2009

The Nath Law Group
112 South West Street
Alexandria, VA 22314

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,482,934

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,482,934, claims of which cover the human drug product OMNARIS® (ciclesonide), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,749 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of a request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,749 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of May 12, 2008 (73 FR 26999). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,893 - 0) + 303 \\ &= 1,749 \text{ days (4.8 years)}\end{aligned}$$

Since the regulatory review period began January 21, 1998, after the patent issued (January 9, 1996), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,482,934
Granted:	January 9, 1996
Original Expiration Date ¹ :	January 9, 2013

¹Subject to the provisions of 35 U.S.C. § 41(b).

Applicant: Jose Calatayud et al.
Owner of Record: NYCOMED GmbH
Title: Pregna-1,4-Diene-3,20-Dione-16-17-Acetal-21
Esters, Process For Their Preparation, Composition,
And Methods For The Treatment Of Inflammatory
Conditions
Product Trade Name: OMNARIS® (ciclesonide)
Term Extended: 1,749 days
Expiration Date of Extension: October 24, 2017

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE By FAX: (571) 273-7728
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to Raul Tamayo at (571) 272-7728.



Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: OMNARIS® (ciclesonide)
Docket No.: FDA-2007-E-0398

Attention: Beverly Friedman